QUALITY ASSURANCE MANUAL

Friedman & Bruya, Inc.

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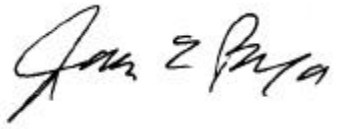
Approved by

Executive Committee Representative: 

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3.0 QUALITY SYSTEM POLICY STATEMENT

Quality Assurance/Quality Control (QA/QC) is of fundamental importance to any chemical testing program. It is the goal of Friedman & Bruya, Inc. (F&BI) to provide analytical data which is scientifically sound and of known and documented quality. To achieve this objective, a quality system has been established to ensure that adequate QA/QC procedures are followed and documented, from sample receipt through to the final report provided to the client. The quality system has been established to meet the requirements of the National Environmental Laboratory Accreditation Program (NELAP). The policies and procedures established are designed to meet the quality requirements of our clients, as well as those of accrediting authorities.

F&BI laboratory management is committed to following good professional practices, and to providing the highest quality of environmental testing services to our clients. An important part of this commitment is the requirement that all F&BI personnel involved with environmental testing activities, including management, are familiar with the established quality system, and implement the policies and procedures of the system in their work.

4.0 ETHICS POLICY STATEMENT

Friedman & Bruya, Inc. (F&BI) believes the practice of chemistry requires training, care, attention to detail and personal integrity that must withstand significant pressure from interested parties. We believe we stand firmly for the chemist's right to practice his/her profession with the highest level of support. For this reason, fraud or the falsification of analytical data by an employee is grounds for immediate dismissal. Management shall review data and perform internal audits to ensure ethical conduct on the part of its employees.

Waste of our clients' time and money, as well as natural resources, is strongly discouraged. Environmental analyses can be very costly and their results exponentially more so. Friedman & Bruya, Inc. was formed to provide our clients with analytical information that met their chemical and analytical needs, while at the same time minimizing cost wherever possible.

Friedman & Bruya, Inc. is proud of its employees. Upon employment, a manual is issued to each employee that describes the policies of Friedman and Bruya, Inc. with regards to employee conduct, fraud, waste and abuse. We believe abuse or harassment is degrading to our employees and our clients. Such behavior is not condoned by Friedman & Bruya, Inc. This covers interactions amongst our employees, as well as those between us and our clients. Where abuse or harassment can be documented, a written warning is issued. If the action or behavior continues, dismissal may result.

All employees of Friedman & Bruya, Inc. are charged with the task of reporting any occurrence of fraud or data falsification to the highest authority within our organization. Management will continually look for fraud and data falsification through standard review practices such as those conducted during the course of data review and internal audits. Management will not attempt to create policies that conflict with our fraud policy. If any employee feels or believes that a management policy conflicts with our fraud policy or that any such policy encourages fraudulent practices on the part of employees, they are encouraged to bring these issues to the attention of their supervisor or to the highest authority within our organization.

5.0 LABORATORY ORGANIZATION

5.1 Ownership and Facility Description

F&BI is a privately owned corporation. No other business affiliations or external business entities exist. The F&BI laboratory is comprised of one building, with approximately 12,000 square feet, which is located at 3012 16 Ave. W., Seattle WA. This laboratory was built with safety, efficiency and quality control in mind. Separate rooms are designated for inorganic, organic and volatiles extractions. Fume hoods are located in each of these rooms as well as in standard storage and preparation rooms. Separate areas are also designated for sample storage, instruments/analysis, office space and records storage. Floor plans of the building can be furnished upon request.

5.2 Personnel Organization

The qualifications and responsibilities for key personnel are listed below. An organizational chart is provided in Figure 5-1.

Laboratory/Technical Director

Qualifications:

The Laboratory/Technical Director should be an individual who has a history of laboratory and personnel management. She/He should have a knowledge of all analyses performed by the laboratory and of QA/QC standards of performance. This person should have a bachelors degree in chemical, environmental, biological sciences, physical sciences or engineering, with at least 24 college semester credit hours in chemistry and with at least 2 years of relevant experience. (A masters or doctoral degree may be substituted for 1 year experience.)

Responsibilities:

The Laboratory/Technical Director reports directly to the Executive Committee. He/She has overall responsibility for the technical operation of the laboratory. Specific responsibilities include the following:

- Monitor standards of performance in quality control and quality assurance.
- Monitor the validity of the analyses performed and data generated to assure reliable data.
- Ensure sufficient numbers of qualified personnel are employed.
- Provide educational direction to laboratory staff.
- Assign workloads and arranges schedules of Project Leaders.
- Evaluate overall effectiveness of the laboratory activity.
- Propose new methods and modifications as needed. Institute new programs and procedures as directed by the Executive Committee.
- Review all new work to ensure that appropriate facilities and resources are available.
- Fill in for the QA Officer in her/his absence.

Quality Assurance Officer

Qualifications:

The Quality Assurance Officer should be an individual who has a history of establishing inter-laboratory and intra-laboratory quality assurance programs. She/He should be capable of evaluating analytical data to distinguish between sample variability, instrument variability and method errors. This person is expected to have a degree in chemistry plus several years practice as an environmental chemist evaluating analytical data for technical validity.

Responsibilities:

The Quality Assurance Officer reports to the Executive Committee and Laboratory/Technical Director. She/He has overall responsibility for the quality system and its implementation. Specific responsibilities include the following:

- Serve as the focal point for QA/QC and be responsible for oversight of quality control data.
- Have general knowledge of the analytical test methods for which data review is performed.
- Have documented training and/or experience in QA/QC procedures.
- Objectively and independently evaluate data and perform assessments.
- Arrange for or conduct internal audits on the entire technical operation annually.
- Act as the collection point for proposed changes in the Quality Assurance Program and propose changes in the program as required.
- Manage laboratory participation in inter-laboratory comparisons and proficiency programs.
- Lead training of laboratory staff in QA policy and objectives.
- Inform laboratory management of deficiencies in the quality system.
- Notify laboratory management and project managers, in writing, of any changes to accreditation.
- Assist in training of analysts in analytical quality control procedures.
- Keep the QA manual and SOPs current.
- Fill in for the Laboratory/Technical Director in his/her absence.

Project Leader

Qualifications:

Project Leaders should be individuals who have a history of analyzing environmental samples. They should have a knowledge of quality assurance and how it relates to the validity of analytical data. They should also have knowledge of the specific analytical testing requirements for the needs of our clients. They should be able to recognize problems which can arise when analyzing samples, and be able to discuss with the client proper analytical techniques for meeting the clients' goals. This person is expected to have a degree in chemistry or several years experience in the environmental chemistry field.

Responsibilities:

The Project Leaders report directly to the Quality Assurance Officer on all quality assurance matters. They report directly to the Technical/Laboratory Director on all other matters such as project status and projected work loads. Specific responsibilities include the following:

- Support the quality assurance program within the project.

- Determine effectiveness of the quality assurance program in the project.
- Recommend to the Quality Assurance Officer changes in the quality assurance program.
- Document for the client any quality control problems which could not be resolved.
- Provide technical overview of laboratory activities.

Laboratory Analysts

Qualifications:

Laboratory Analysts should be individuals who have a history of analyzing environmental samples. They should have a knowledge of quality assurance. They should recognize quality assurance results which are out of conformance and be able to determine and remedy possible causes. Laboratory Analysts are expected to have a degree in chemical, environmental, biological sciences, physical sciences or engineering and/or experience in the environmental chemistry field.

Responsibilities:

Specific responsibilities include the following:

- Perform analytical procedures and data recording in accordance with accepted methods.
- Consult with the Quality Assurance Officer to verify that the laboratory is meeting stated quality control goals.
- Evaluate new analytical techniques, procedures, instrumentation and quality control methods, and provide recommendations to the Technical/Laboratory Director and Quality Assurance Officer.
- Lead the training of new analysts in laboratory operations and analytical procedures.
- Evaluate instrument performance and implement instrument calibration and preventive maintenance program.
- Perform data processing and validation.
- Initiate non-conformance report forms for out-of-control situations, instrument malfunction, calibration failure, or other non-conformances as appropriate.
- Prepare and maintain laboratory quality control records.

General Personnel

Qualifications:

General personnel include all other staff, such as laboratory technicians, sample check-in technicians and office personnel. General personnel should be individuals that pay very close attention to detail and follow written and oral instructions precisely.

Responsibilities:

General personnel are responsible for following established procedures and reporting any quality control problems or questions.

Figure 5-1
Laboratory Organization

Executive Committee:
Responsibilities: Appointed by owner to oversee all operations and functions of the laboratory.

Laboratory/Technical Director:
Responsibilities: Reports directly to the Executive Committee.

Quality Assurance Officer:
Responsibilities: Reports directly to The Executive Committee and Laboratory/Technical Director.

Project Leaders:
Responsibilities: Report directly to the Quality Assurance Officer on QA/QC matters and to the Technical/Laboratory Director on all other matters.

Laboratory Analysts/Calculations Chemists:
Responsibilities: Report directly to the Quality Assurance Officer on QA/QC matters and to the Technical/Laboratory Director and/or Executive Committee on all other matters.

Laboratory Analyst/Extraction Manager:
Responsibilities: Reports directly to the Quality Assurance Officer on QA/QC matters and to the Technical/Laboratory Director and/or Executive Committee on all other matters.

Technicians:
Responsibilities: Report directly to the Extraction Manager.

Safety Officer/Committee:
Responsibilities: Reports directly to the Technical/Laboratory Director and/or Executive Committee.

General Personnel:
Responsibilities: Reports directly to the Executive Committee.

6.0 STANDARD OPERATING PROCEDURES

Standard operating procedures (SOPs) are maintained which accurately reflect current laboratory activities. These documents may include, for example, equipment manuals provided by the manufacturer, published analytical methods with any changes or specifications documented, or internally written documents. Hardcopies of all SOPs are organized in folders which are easily accessible to all personnel. (The exception is equipment manuals, which are kept with the corresponding equipment.) There are two general types of SOPs; method SOPs and administrative SOPs. A list of administrative SOPs, along with other quality system documents, is included in Appendix A.

Method SOPs

Method SOPs are generated for each accredited method performed by F&BI. They provide detailed, laboratory specific, procedures for analytical testing methods. Each method SOP references the published analytical procedure upon which it is based. When the referenced analytical procedure has stated QA/QC requirements, the SOP meets the stated requirements. Any additional, laboratory specific, QA/QC requirements are detailed in the method and/or administrative SOPs.

Administrative SOPs

Administrative SOPs provide detailed procedures for all activities of the quality system not included in specific analytical methods, such as sample receiving, personnel training, and creating client reports. Administrative SOPs may be separate documents, or may be included in this document.

6.1 Deviation from SOPs

When a client (or project) has specific requirements of the laboratory, a deviation from existing procedures may be necessary. Typical examples include addition of target analytes and project specific reporting limits. If a deviation is requested, the project manager is responsible for discussing the request with the manager in charge of the analysis and obtaining her/his approval to accept the project. The project manager is also responsible for documenting the request on the appropriate analysis extraction worksheets, and on the final report if necessary.

Deviations from SOPs are documented using the extraction worksheet, sequence tables, injection logs, and/or other documents such as the non-conformance report form as discussed in section 13.3. Frequent departure from policy is not encouraged. However, if frequent departure from a particular policy is noted, the technical/laboratory director will address the possible need for a change in the policy.

7.0 TRAINING

Our company is designed around the idea that our employees are our most valuable asset. We are committed to the professional development of our employees. Since we are a relatively small laboratory, many of our employees wear several hats, and cross training is critical.

7.1 Quality System, Data Integrity, and Safety Training

When hired, each employee receives a company policy manual, data integrity SOP, quality assurance manual, and any SOPs relevant to their responsibilities. She/he also receives a safety training form and an employee attestation form, including data integrity training, to fill out and sign. The office manager is responsible for providing each new employee with copies of the policy manual and quality assurance manual. The QA officer is responsible for providing each employee with safety and general training forms, and copies of the relevant SOPs. Each employee is responsible for completing the required training documents, and for complying with all QA/QC and data integrity requirements. Each employee is also responsible for maintaining the current quality system documents which are relevant to their position, in their individual document file.

7.2 Initial Demonstration of Capability

The first step in training for analytical procedures is to familiarize the trainee with the method. This is achieved through a combination of reading the method SOP and observing an experienced analyst performing the method. The trainee then performs the method under close supervision. Prior to independently performing an analysis, each analyst completes an initial demonstration of capability (DOC). The DOC is performed as follows:

- Obtain a quality control sample from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.
- Dilute/prepare enough of the QC sample to make 4 separate aliquots (samples) of the specified concentration. If the concentration is not otherwise specified, it should be approximately 10 times the MDL. Laboratory control samples or MDL study samples may be used to meet this requirement.
- Extract and/or analyze each of the 4 samples either concurrently or over a period of days.
- Use all of the results to calculate the mean recovery (accuracy) and the standard deviation (precision) for each parameter/analyte. Compare the mean and standard deviation to method acceptance criteria.
- If all parameters/analytes meet the acceptance criteria, the DOC is complete and independent analysis of actual samples can begin. If one or more of the parameters/analytes fail at least one of the acceptance criteria, then locate and correct the source of the problem and repeat the entire test (above) for either all of the parameters/analytes or just the parameter(s)/analyte(s) that failed.

7.3 Continuing Demonstration of Capability

At least one of the following, once per year, is completed by each analyst to demonstrate continuing proficiency.

- Acceptable performance of a blind sample
- Another demonstration of capability
- At least four consecutive laboratory control samples with acceptable levels of precision and accuracy (calculated as for DOC above).
- Successful analysis of a blind performance sample on a similar test method using the same technology (e.g. GC/MS volatiles by methods 624 and 8260 are considered equivalent).
- If none of the above can be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.

7.4 Continuing Quality System, Data Integrity, and Safety Training

Company wide training meetings are held at least once a quarter. At these meetings quality system, data integrity, and/or safety topics are discussed by the QA officer, technical/laboratory director, and/or safety officer/committee respectively. Employees are also encouraged to participate in relevant external training, such as seminars and instrument training courses.

7.5 Documentation of Training

Documentation of education, experience and training prior to employment at F&BI is kept on file with personnel records. The office manager is responsible for maintaining personnel records. All employees document on the Employee Attestation Form that they have read, understood and will follow the Policy Manual, QA Manual and each SOP distributed to him/her. The attendance at each quarterly training meeting is documented using the Quarterly Training Meeting form. These and other completed training documents, including DOC certificates, are filed. In addition a database summarizing DOC training is maintained. The QA officer is responsible for maintaining the DOC database. The office personnel are responsible for maintaining training files. Additional details of training documentation are found in the "Training" SOP.

8.0 MATERIAL PROCUREMENT AND CONTROL

The quality of reagents, solvents, gases, water, and laboratory vessels used in analyses should be known so that their effect upon analytical results can be defined and anticipated. Materials and equipment purchased by F&BI should meet the requirements stated below or as denoted in specific analytical procedures, and be controlled as stated.

The following general guidelines are used for purchasing and using materials and equipment. More specific requirements can be found in section 9 below, and in administrative and method SOPs.

- Specify within the purchase requests the suitable grades of materials.
- Verify upon receipt that materials meet requirements and that, as applicable, material certificates/records are provided and maintained in the laboratory record system.
- Date all chemicals, standards and reagents with date of receipt, date opened and expiration date.
- Store reagents and solvents in accordance with manufacturer's recommendations.
- Verify that material storage is properly maintained, and remove materials from use when shelf life has expired.
- Record the date put into service for equipment such as balances and analytical instruments.
- Record preventive and corrective maintenance procedures performed on equipment.
- Verify that equipment, including analytical balances, thermometers, volumetric glassware etc., is properly calibrated prior to use.
- Clearly mark any equipment which has been taken out of service.

8.1 Requirements for Reagents, Solvents, and Gases

Chemical reagents, solvents, and gases are available in a variety of grades of purity, ranging from technical grade to ultrapure grades. The purity required varies with the type of analysis and project requirements. For many analyses analytical reagent (AR) grade is satisfactory. Other analyses, such as trace organic analyses, frequently require special ultrapure reagents, solvents, and gases.

General Inorganic Analyses

In general, AR grade reagents and solvents are adequate for inorganic analyses. Primary standard reagents should be used for standardizing all volumetric solutions. All prepared reagents should be checked for accuracy.

Trace Metals Analyses

All standards used for emission spectroscopy should be spectro-quality. It is recommended that other reagents and solvents also be spectro-quality. In many cases, AR grade may be satisfactory. Standards are prepared by the analyst, or purchased provided that purchased materials meet the requirements of the analytical method. Fuel and oxidant gases used for emission spectroscopy should be high purity.

Organic Chemical Analyses

AR grade is generally the minimum acceptable grade for materials used for organic analyses. Reference grade standards should be used as necessary. Pesticide-quality solvents are generally required for low-concentration work. AR grade solvents are adequate for analyzing industrial waste samples. However, the contents of each solvent lot should be checked to determine suitability for the analyses.

For sample cleanup procedures, the adsorbents most commonly used are florisil, silica gel, and alumina. These are pre-activated according to the analytical method requirements and checked for interfering constituents.

Water

Deionized water is used for dilution and preparation of reagent solutions. Deionized water prepared in the laboratory should be ASTM Type I or better. For trace level inorganic work, Type II Reagent grade is required. Organic-free water is required for organic analyses. Organic-free water may be verified by GC or GC/MS. However, when determining trace organics by solvent extraction and gas chromatography, specialty water such as HPLC grade water with sufficiently low background may need to be used.

8.2 Requirements for Laboratory Containers

Containers used in the laboratory can affect the quality of results. Material composition and volumetric tolerances are discussed below.

Material Composition of Laboratory Vessels

The glass recommended for general use is chemically resistant borosilicate glass, such as that manufactured under the trade names of Pyrex or Kimax. The use of plastic vessels, containers and other apparatus made of Teflon, polyethylene, polystyrene, and polypropylene is desirable for certain specified applications.

Volumetric Tolerances of Laboratory Vessels

All volumetric measurements are made using measuring devices with tolerances appropriate to the level of accuracy needed.

Glassware Cleaning Requirements

All glassware used for sample extraction and analysis is cleaned sufficiently to meet the sensitivity of the method. This is tested on an ongoing basis with method blank samples. The same types of glassware and glassware cleaning techniques are used for method blank samples and client samples. In general, the following glassware cleaning procedures are followed.

- Beakers - wash with laboratory grade soap, triple rinse with water
- Separatory funnels - remove stopcock, wash stopcock, cap and funnel with laboratory grade soap, triple rinse with water, triple rinse with extraction solvent
- KD flasks - wash with laboratory grade soap, triple rinse with water, triple rinse with extraction solvent
- Snyder columns - triple rinse with extraction solvent
- Concentrator tubes - wash with laboratory grade soap, triple rinse with water, triple rinse with extraction solvent
- Syringes - triple rinse with extraction solvent

If lower than normal reporting limits are required or if highly contaminated samples have been extracted, glassware may need additional cleaning such as acid rinsing.

9.0 MEASUREMENT TRACEABILITY AND CALIBRATION

All measuring operations and testing equipment having an effect on the accuracy or validity of analytical results are calibrated and/or verified prior to being put into service and on a continuing basis. Wherever possible, reference standards (such as Class 1 weights and traceable thermometers) and analytical reagent calibration standards are traceable to national standards of measurement. For accredited analyses, where traceability to national standards is not applicable, correlation of results is confirmed using proficiency testing and/or independent analysis.

All equipment and reference materials necessary for correct performance of analysis are under the permanent control of F&BI. A list of major analytical equipment is given in Appendix B.

9.1 Support Equipment Calibration

Support equipment includes devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, thermometers, ovens, refrigerators, freezers, water baths and volumetric dispensing devises such as autopipetes and syringes. In cases where quantitative results are dependent on their accuracy, these devices are calibrated as described below.

Calibration/Verification Prior to Use

When new support equipment is purchased, it is the responsibility of the extraction manager to verify its calibration and traceability prior to putting it into service. Each piece of equipment is numbered, or otherwise identified, and the date put in service is recorded. Any certificates provided by the manufacturer are marked with the equipment identification and kept on file. Specific procedures for calibration (including on-going calibration) of specific types of support equipment are detailed in the “Support Equipment Monitoring and Calibration" SOP. These procedures include:

- reference standard(s) used for calibration
- specific calibration technique employed
- acceptable performance tolerances
- calibration frequency
- documentation procedures

On-Going Calibration

Requirements for on-going calibration are provided in the specific equipment SOPs. The requirements are based on the type of equipment, stability characteristics of the equipment, and required accuracy. Some equipment is calibrated each working day, some monthly and some less frequently. All support equipment is calibrated annually, using nationally traceable reference standards if possible, over the entire range of use. It is the responsibility of the extraction manager to complete all on-going calibrations.

Corrective Actions

If equipment does not meet the calibration requirements, it is taken out of service unless and until necessary repairs have been made. All such equipment is marked as “out of service” and, if possible, placed in a different location until repaired. Records of

all repairs, including service calls, are kept with the equipment records. When a piece of equipment is repaired another initial calibration is performed prior to being put back into service. If equipment cannot be repaired, it is discarded as appropriate. It is the responsibility of the laboratory manager to mark out of service equipment, arrange for repairs, re-calibrate and document all such activities.

In addition, if equipment goes outside the direct control of the laboratory, it is the responsibility of the extraction manager to verify satisfactory function and calibration status before the equipment is returned to service.

If an item of equipment is found to be defective, the effect of the defect on previous calibrations or analyses is examined, and corrective actions are taken if necessary. It is the responsibility of the person who finds a defect to inform the QA officer.

9.2 Instrument Calibration

Initial instrument calibration and continuing instrument calibration verification of all analytical instruments is performed to ensure that the data is of known quality. Specific method SOPs describe detailed calibration requirements for each method. It is the responsibility of each analyst to follow and document established calibration procedures. The following sections describe the calibration requirements for all accredited analysis performed by F&BI.

Initial Calibration

The following are essential elements of initial instrument calibration:

- Sufficient raw data records are retained to permit reconstruction of the calibration.
- Sample results are quantitated against the initial calibration, and may not be quantitated from any continuing instrument calibration verification.
- Initial calibrations are verified with a second source standard (a standard obtained from a second manufacturer or lot, if the lot can be demonstrated from the manufacturer as prepared independently from other lots), unless a different requirement is specified in the method.
- Appropriate criteria for the acceptance of an initial calibration are established.
- If the initial calibration results are outside of the established acceptance criteria corrective action is taken (see below).
- Any reported sample results which fall outside of the calibration range are reported as having less certainty.
- At least one calibration standard is at or below the method reporting limit.
- The lowest calibration standard is above the method detection limit (MDL), with the following exception:

For instrument technology (such as ICP/MS) with validated techniques which use a zero point and a single point calibration standard, the following apply:

- Prior to analysis of samples the linear range is established.
- Zero point and single point calibration standard are analyzed with each analytical batch. Additional standards may also be analyzed.
- A standard corresponding to the limit of quantitation is analyzed with each analytical batch.
- The linearity is verified at a frequency established by the method and/or the manufacturer.

Continuing Instrument Calibration Verification

When the initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration is verified prior to sample analysis by a continuing instrument calibration verification (CCV). The following items are essential elements of continuing instrument calibration verification:

- A CCV is repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification are varied within the established calibration range. If an internal standard is used, only one CCV is analyzed per batch.
- Sufficient raw data records are retained to permit reconstruction of the CCV. These records explicitly connect the continuing verification data to the initial instrument calibration.
- Criteria for the acceptance of a CCV are established.
- If the CCV results are outside established acceptance criteria, corrective actions are performed (see below).

Corrective Actions

Specific corrective actions are included in method SOPs. Following are general corrective action guidelines:

- If the initial calibration results are outside established acceptance criteria, corrective actions are performed. This may include preparation of new standard solutions or instrument maintenance. Data associated with an unacceptable initial instrument calibration should not be reported. However, if such data is reported (usually due to insufficient sample for reanalysis) then it is reported with appropriate qualifiers.
- If a CCV falls outside of established acceptance criteria, then corrective actions are performed. This may include preparation of new standard solutions or instrument maintenance. If routine corrective action procedures fail to produce a second consecutive (immediate) CCV within acceptance criteria, then either acceptable performance is demonstrated after corrective action with two consecutive CCVs, or a new initial calibration is performed. If possible, samples associated with a failing CCV are reanalyzed. If reanalysis is not performed, then results are qualified. In the following two situations, results may be reported, even if reanalysis is possible.
  a) If the CCV fails high, then associated sample results which are non-detect may be reported.
  b) If the CCV fails low, then associated sample results which are above a level which provides sufficient data for client use (if known) may be reported.

9.3 Maintaining Traceability of Standards, Solvents, and Reagents

The following steps are taken to maintain traceability of standards.

- All standards are logged into the Standards Logbook and given a Date Code which is written on each container and certificate (if included). Also recorded are description, supplier and manufacturer's Lot # (if provided). The sample check-in technician, is responsible for logging in standards.
- When opened, all original containers (as provided by the vendor) are labeled with the date opened and an expiration date (based on the date opened). The extraction analyst is responsible for labeling original containers when opened.
- Documentation of standards prepared from purchased stocks or neat compounds is maintained in the Standards Prep Logbook. Information recorded includes the Date Code, the preparation date, the expiration date, the amount used, and the preparer's initials. The person preparing the standard is responsible for proper documentation.
- Containers of prepared standards are labeled with a unique Standards Prep Logbook ID linking them to the above preparation documentation. They are also labeled with the preparation and expiration dates. The person preparing the standard is responsible for labeling correctly.
- Whenever a standard is used for sample extraction or analysis (e.g. calibration standard, surrogate, etc.) the Standards Prep Logbook ID is written in the sample extraction and analysis records. The extraction analyst is responsible for recording the Logbook ID.
- Standards are not used past their expiration dates.

The following steps are taken to maintain traceability of solvents and reagents.

- All solvents and reagents are logged into the Solvents and Reagents Logbook and assigned a Solvent Code which is written on each container and certificate (if included). Also recorded are description, supplier and manufacturer's Lot # (if provided). The sample check-in technician, is responsible for logging in solvents and reagents.
- When a solvent or reagent is used to prepare a standard, the Solvent Code is recorded in the Standards Prep Logbook. The person preparing the standard is responsible for proper documentation. Note: If a reagent solution is prepared, then that is documented in the Standards Prep Logbook as described above.
- When a solvent or reagent is used for extraction or analysis, the Solvent Code is recorded in the sample extraction and analysis records. The extraction analyst is responsible for recording the Solvent Code.

9.4 Equipment Maintenance

Preventive maintenance is an important part of the F&BI quality system. A maintenance program has been outlined to provide an organized program of actions to maintain proper instrument performance which will ensure reliability of the measurements and prevent instrument failure during use. This equipment maintenance program is included as Appendix C. Additional information about routine

and special maintenance activities can be found in instrument manuals and troubleshooting guides, and in method SOPs.

Implementation

The implementation of the preventive maintenance program is dependent upon the specific instruments and equipment used. The extraction manager is responsible for performing and/or coordinating all support equipment maintenance. The GC, GC/MS, and inorganics supervisors are responsible for performing and/or coordinating all analytical instrument maintenance.

Documentation

Preventive maintenance is documented in maintenance log books. Each instrument has its own maintenance logbook which is updated each time any type of work is performed on the instrument.

10.0 SAMPLE HANDLING PROCEDURES

10.1 Sampling and Sample Acceptance Policy

The quality of analytical results is highly dependent upon the quality of the procedures used to collect, preserve and store samples. Factors that are taken into account to ensure accurate, reliable results include:

- Type of container used
- Sample preservation
- Amount of sample taken
- Sample storage (holding) time
- Proper sample labeling/identification
- Proper chain-of-custody (COC) documentation

Container, volume, preservation and holding time information for selected analyses for water and soil samples is included in Appendix D. F&BI provides sample containers, including preservative, to our clients when requested.

Each sample container should be labeled, using a durable label and indelible ink, to identify the following:

- Client name
- Client project name
- Sampling date and time
- Sample name/number
- Sample preservation

A chain-of-custody (COC) form should be filled out for every client project. F&BI's COC is shown in Figure 10-1. The following information should be included on the COC:

- Client (company) name and contact information
- Client project name/number
- Sampler's name
- Sample ID (name/number)
- Date and time sampled
- Type of sample (e.g. soil, water, etc.)
- Requested analysis

Sample Acceptance Policy

It is the client's responsibility to follow proper sampling and documentation protocol. If any samples are received with incomplete documentation, unclear sample labeling, incorrect or damaged sample containers, expired holding time, insufficient sample volume, incorrect sample preservation or any other circumstances that could affect data quality, the sample custodian and/or project manager will notify the client. If the problem can be resolved (e.g. documentation provided) normal analysis will be initiated. If not, data will be reported with qualifiers if necessary. The sample acceptance policy is posted at the sample receiving area, and copies are available upon request.

10.2 Sample Receipt Protocols

Chain-of-Custody

Evidence of sample collection, shipment, laboratory receipt, and laboratory custody until disposal is documented to maintain quality control. Documentation is accomplished through the COC records, shipping records and sample check-in and disposal records.

Sample Condition

Upon receipt, the condition of the samples is recorded. A copy of the sample condition receipt checklist is included in Figure 10-2. If a sample does not meet the sample receipt acceptance criteria the client is consulted for further instructions before proceeding. A record of the client's request is retained.

Sample Tracking

A permanent chronological sample receipt logbook is used to document receipt of all samples. The laboratory project number assigned is recorded on the sample condition checklist and on the COC, providing an unequivocal link to the laboratory and field ID's, the sample collection and analysis information provided on the COC, and the sample condition record.

Each sample received is assigned a unique laboratory ID that maintains an unequivocal link with the unique field ID assigned to each container. The laboratory ID is placed on the sample container as a durable label and is recorded on the COC. The laboratory ID is the link that associates the sample with subsequent laboratory activities such as sample preparation or calibration.

Sample Check-In

Upon sample receipt, the sample custodian completes the following steps (more details are found in the "Sample Receiving" SOP):

- Sign and date the COC and attach the waybill (if applicable) to the COC.
- Examine all samples and accompanying paperwork, using the Sample Condition Upon Receipt Checklist as a guide.
- Verify that sample holding times have not been exceeded and are not close to their limit.
- Notify the Project Leader if there are any samples that should be analyzed immediately because of holding time or client request.

The sample custodian then logs the samples into the Sample Check-In Logbook, which contains the following information:

- Date received in laboratory
- Name of client
- Client project name/number
- Type and condition of samples as received
- Analyses requested
- F&BI project number
- Initials of person logging in samples
- Container size(s) and cooler/sample temperature

The sample custodian then initiates sample analysis by:

- Completing the COC documentation
- Labeling each container with the unique laboratory ID
- Placing the samples in proper laboratory storage
- Notifying the project leader of sample arrival by placing copies of the COC and all other project documents in the project leader bin.

10.3 Sample Storage

Samples and sample extracts are stored according to the conditions specified by preservation protocols. The temperatures of sample storage refrigerators are monitored each working day and recorded in the refrigerator temperature logbook. Samples and sample extracts are stored away from all standards, reagents, food and other potentially contaminating sources, and are stored in such a manner to prevent cross contamination. In addition, samples and sample extracts are stored in a secured area in order to protect sample condition and integrity. Placing of samples in the proper storage environment is the responsibility of the sample custodian. Placing of extracts in the proper storage environment is the responsibility of the extraction analyst.

10.4 Sample Disposal

There are several possibilities for sample disposition:
- The sample may be consumed during analysis.
- Samples may be returned to the client for disposal.
- Samples are incorporated into the laboratory waste streams.

The samples may be stored for 30 days after arrival. Proper environmental control and holding times are observed if reanalysis is anticipated. If reanalysis is not anticipated, environmental conditions for storage may not be observed.

The project leader and/or sample custodian determine disposition of samples if not specified on the COC. In general, F&BI will not maintain samples and extracts longer than one month beyond completion of analysis, unless otherwise requested.

After the appropriate storage time, the samples and extracts are disposed of by following approved disposal procedures. All materials known or suspected to contain hazardous substances are disposed of as separate waste streams. F&BI has identified 4 primary waste streams; solid waste, organic liquid waste, PCB waste, and acid waste. Disposal procedures are in compliance with all EPA, DOT, and Washington State waste disposal regulations. The extraction manager is responsible for overseeing sample and waste disposal.

Figure 10-1
Chain of Custody Form

SAMPLE CHAIN OF CUSTODY

Page # _____ of _____

Send Report To _____
Company _____
Address _____
City, State, ZIP _____
Phone # _____ Fax # _____

SAMPLERS *(signature)*

PROJECT NAME/NO. | PO #

REMARKS

TURNAROUND TIME
- ☐ Standard (2 Weeks)
- ☐ RUSH

Rush charges authorized by:

SAMPLE DISPOSAL
- ☐ Dispose after 30 days
- ☐ Return samples
- ☐ Will call with instructions

Sample ID	Lab ID	Date	Time	Sample Type	# of containers	ANALYSES REQUESTED: TPH-Diesel	TPH-Gasoline	BTEX by 8021B	VOCs by 8260	SVOCs by 8270	HPS					Notes

	SIGNATURE	PRINT NAME	COMPANY	DATE	TIME
Relinquished by:					
Received by:					
Relinquished by:					
Received by:					

Friedman & Bruya, Inc.
3012 16th Avenue West
Seattle, WA 98119-2029
Ph. (206) 285-8282
Fax (206) 283-5044

Figure 10-2

SAMPLE CONDITION UPON RECEIPT CHECKLIST

PROJECT # _____ **CLIENT**_____ **INITIALS/ DATE:**_____

If custody seals are present on cooler, are they intact?	NA	YES	NO
Cooler/Sample temperature		_____	C
Were samples received on ice/cold packs?		YES	NO
Number of days samples have been sitting prior to receipt at laboratory		_____	days
Is there a Chain-of-Custody* (COC)? *or other representative documents, letters, and/or shipping memos		YES	NO
Are the samples clearly identified? (explain "no" answer below)		YES	NO

Is the following information provided on the COC* ? (explain "no" answer below)

Sample ID's	Yes	No	# of Containers	Yes	No
Date Sampled	Yes	No	Relinquished	Yes	No
Time Sampled	Yes	No	Requested analysis	Yes	No

Were all sample containers received intact (i.e. not broken, leaking etc.)? (explain "no" answer below)		YES	NO
Were appropriate sample containers used? (explain "no" answer below)		YES	NO
If custody seals are present on samples, are they intact?	NA	YES	NO
Are samples requiring no headspace, headspace free?	NA	YES	NO

Explain "no" items from above (use the back if needed)

_____

_____

_____

_____

Are samples for PCB testing (if yes, put a red sticker on each sample)		YES	NO
Did samples originate out of the country? (if yes, put in APHIS refrigerator)		YES	NO

Was client notified of sample receipt? Over the Counter Picked up by F&BI

YES NO (explain)

If Yes, name of person contacted Left Message

Special Instructions from Client_____

_____

11.0 QUALITY CONTROL OBJECTIVES

F&BI follows a comprehensive internal quality control (QC) program to insure precision, accuracy, and reliability of data. QC objectives are established to determine if data generated is acceptable. These objectives are either specified by the method, or are statistically derived from historical laboratory data. Individual method SOPs include details of method QC requirements, which may supersede those given here.

11.1 Demonstration of Capability

Prior to using any test method, and at any time there is a significant change in instrument type or test method, a demonstration of capability (see section 7.2) is performed. In general, this does not test the performance of the method in real world samples, but in the applicable clean matrix.

11.2 Precision

Precision is a measure of the reproducibility of a result. Except as otherwise specified by a an accredited method, the QC objective for precision is 20% as measured by Relative Percent Difference (RPD), as determined by duplicate analyses. It is recognized that for analytes at concentrations of less than five to ten times the method detection limit (MDL), it may be difficult to meet this objective.

Precision is usually expressed as Relative Percent Difference (RPD) based on duplicate analyses of a sample. The RPD is calculated as:

$$RPD = \frac{|X1 - X2|}{[(X1+X2)/2]} \times 100$$

where X1 and X2 are, respectively, the first and second values obtained for the analysis. Precision may be evaluated from duplicate sample, matrix spike and/or laboratory control sample analyses.

11.3 Accuracy

Accuracy is a measure of the closeness of a result to the true or expected value. It is generally determined using matrix spike and/or laboratory control sample recoveries. Control charts (see section 11.4) are generated to calculate laboratory specific accuracy objectives. For accredited analysis without enough QC data, or where the method specifies accuracy objectives, method prescribed limits are used. If the method does not specify control limits, then reasonable default limits are used. It is recognized that, for matrix spike samples, unless the sample is homogeneous and the spike concentration is greater than or approximately equal to the native concentration and greater than five to ten times the reporting limit, this objective may be difficult to meet, and therefore such samples will not be used to generate new QA/QC objectives/criteria. Alternatively, accuracy may be assessed through the analysis of appropriate standard reference materials or certified standards or samples, as available.

Accuracy is usually expressed as percent recovery (%R). The %R is calculated as:

$$\%R = ((Xs - Xa)/Ct) \times 100$$

where Xs is the observed concentration of the spiked sample, Xa is the observed concentration of the unspiked sample, and Ct is the concentration of the spike.

11.4 Uncertainty

Laboratory generated control limits (see below) for laboratory control samples represent an estimation of the uncertainty of measurement for a particular analysis.

Control Limits

Control limits are the acceptance criteria used for evaluating the accuracy and precision of results. F&BI has established control limits for precision of 0% to 20% for all accredited analyses, unless method specified limits are more stringent. Initial control limits for accuracy are taken from the method or regulatory requirements. If no method or regulatory criteria exist, control limits are assigned default values. These default values are assigned using the following guidelines.

- For laboratory control samples default control limits are 70% to 130%, and default warning limits are 80% to 120%.
- For matrix spike samples and surrogate compounds default control limits are 50% to 150%, and default warning limits are 65% to 135%.
- Established control limits for a similar method/matrix may be used instead of default limits.

When sufficient data has been generated, the laboratory specific acceptance limits for accuracy are usually generated. After a minimum of 20 samples have been analyzed for a particular matrix/method, the mean and standard deviation of the results are calculated. Warning limits are set at 2 standard deviations from the mean, and control (action) limits are set at 3 standard deviations from the mean. Control limits are generally reviewed at least monthly, or when sufficient data has been generated to warrant review, and updated annually.

Control Charts

Control charts are prepared for accredited analytical methods to document the trends in percent recoveries (accuracy) for laboratory control samples, matrix spike samples and surrogates. Results are monitored routinely by the analyst. If 10 consecutive results fall outside of warning or control limits (either all 10 above, or all 10 below), the cause is investigated and necessary corrective actions are taken.

11.5 Completeness

Completeness is determined as the percentage of the sample data for which the associated QC data is found to be acceptable. The QC goal for completeness, as determined by the percentage of valid data generated, is 100%. Precision and accuracy determinations, if outside the QA objectives due to sample-related causes, may be regarded as qualifying, rather than invalidating, the associated data.

11.6 Representativeness

Representativeness is the degree to which the field sample represents the overall sample site or material. F&BI will make every reasonable effort to assure that the samples are adequately homogenized prior to taking aliquots for analysis, so that the reported results are representative of the sample received. However, F&BI does not represent that the samples submitted for analysis are representative of the conditions in the field. Of particular importance is that mixing may substantially lower the measured levels of volatile components. (For this reason, mixing is avoided as much as possible for samples being analyzed for those compounds.)

11.7 Comparability

Comparability is an expression of the confidence with which one data set can be compared to another. To ensure comparability, standard operating procedures as defined in the quality system are used for handling and analysis of all samples. In addition, F&BI recommends that clients send 2-5% sample duplicates to secondary laboratories in order to assess the comparability of the data to similar data sets generated by other methods and laboratories.

11.8 Method Detection Limits and Reporting Limits

Method Detection Limits

The method detection limit (MDL) is the minimum concentration that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. For each applicable test method and matrix, MDLs are determined for the compounds of interest by spiking the analyte(s) at a level approximately 5 times the expected MDL into a clean matrix and processing as a sample. A minimum of seven replicates are processed and the mean result is multiplied by the applicable students' t value to obtain the MDL. MDLs are determined for each new test method (prior to sample analysis), annually, and each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the reliability of the analysis.

Reporting Limits

Reporting limits (RL), or practical quantitation limits (PQL), are the routinely reported lower limits of quantitation. RLs are calculated from the MDL and are typically 2 to 10 times the MDL. The RLs take into account the day-to-day fluctuations in instrument reliability and other factors. These RLs are the levels to which F&BI routinely reports results. If a result below the RL is reported, typically due to client request, it is qualified as an estimated value.

12.0 ANALYSIS AND EVALUATION OF QUALITY CONTROL SAMPLES

Quality control samples are routinely analyzed with each analytical batch (see below) of field samples to demonstrate that the laboratory is operating within the QC objectives. QC samples are evaluated on an on-going basis, and QC acceptance criteria are defined and used to determine the validity of the data. Specific types of QC samples are described below. Individual method SOPs include details of method QC requirements. A summary of frequency and acceptance limit requirements for QC elements described in this and previous sections is given in Table 12-1. If method requirements are different than those given here, the method requirements will be followed.

12.1 Preparation Batch

The preparation batch is the basic unit for quality control. To ensure that QC results for accredited analyses are representative, all of the samples in a batch, both field and QC samples, are extracted, analyzed and calculated in the same way. In the absence of specific program or method requirements, the requirements for a preparation batch are as follows:

- A maximum of 20 (field) samples are in a batch.
- All samples in a batch are the same matrix.
- QC samples (see below) processed with a batch are; 1 method blank, 1 LCS, 1 MS (if suitable), and either 1 MSD or 1 matrix duplicate (if suitable, if not, then 1 LCSD).
- The same reagent lot(s) are used to process the batch.
- The same analyst(s) process the entire batch.
- The maximum time between the start of processing of the first and last sample in a batch is 24 hours.
- QC samples are prepared and analyzed with the associated field samples. However, if field samples in the batch are reanalyzed for a reason not affecting the QC samples (e.g. dilution, surrogate recovery etc.), the QC samples do not require analysis each time a field sample from the preparation batch is analyzed.
- Each batch is assigned a unique ID which links it to the associated field samples.

12.2 Method Blank Samples

Purpose
The method blank is used to assess the preparation batch for possible contamination during the preparation and processing steps. It is processed along with and under the same conditions as the associated samples.

Frequency
One method blank is analyzed with each preparation batch.

Composition
The method blank consists of a matrix that is similar to the associated samples and is free of the analytes of interest.

Evaluation Criteria and Corrective Action
The goal is to have no detectable contaminants. If contamination is detected in the method blank sample, the nature of the interference and the effect on the analysis of each sample in the batch is evaluated. The source of contamination is investigated and measures taken to minimize or eliminate the problem. Affected samples are reprocessed, or data is appropriately qualified if:

- The concentration of a targeted analytes in the blank is at or above the reporting limit AND is greater than 1/10 of the amount measured in the sample.
- The blank contamination otherwise affects the sample results as per the test method requirements or the individual project data quality objectives.

Results of method blank analyses are maintained with the corresponding analytical data set and reported with project results.

12.3 Laboratory Control Sample (LCS)

Purpose
The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps.

Frequency
One LCS is analyzed with each preparation batch. Exceptions are for analytes for which no spiking solutions are available such as total suspended solids, pH or turbidity.

Composition
The LCS is a controlled matrix, free of the analytes of interest, spiked with known and verified concentrations of analytes. Alternatively the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM). All analyte concentrations are within the calibration range of the methods. The components spiked are specified in individual method SOPs.

Evaluation Criteria and Corrective Action
LCS results are calculated in percent recovery (see section 11.3). Results are compared to established acceptance criteria. A LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. If a LCS result is found to be outside the criteria, this indicates that the analytical system is “out of control”. Any affected samples associated with an out of control LCS are reprocessed and re-analyzed (if possible), or the results reported with appropriate data qualifying codes. LCS results are reported on the quality control data summary forms.

12.4 Matrix Spike (MS) and Matrix Spike Duplicate (MSD) Samples

Purpose
Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and is not normally used to determine the validity of the entire batch.

Frequency
One MS sample is analyzed with each preparation batch, if a sufficient amount of sample is provided.

Composition
MS/MSD analysis is performed on aliquots of actual samples. The composition is not usually known. Samples are spiked with known and verified concentrations of analytes. All analyte spiking concentrations are within the calibration range of the methods. The components spiked are specified in individual method SOPs.

Evaluation and Corrective Action
The results from MS/MSD analyses are primarily designed to assess the precision and accuracy of analytical results in a given matrix and are expressed as percent recovery (%R) and relative percent difference (RPD) (see section 11). Results are compared to the established acceptance criteria. If results are outside the criteria, the cause is investigated and corrective actions are taken if necessary, or the MS/MSD data is reported with appropriate qualifiers. MS/MSD results are reported on the quality control data summary forms.

12.5 Matrix Duplicate Samples

Purpose
Matrix duplicates are replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method.

Frequency
One duplicate sample is analyzed with each preparation batch. If sufficient sample is provided, this will be either a MSD or a matrix duplicate. If not, a laboratory control sample duplicate (LCSD) is analyzed.

Composition
Matrix duplicates are performed on replicate aliquots of actual samples. The composition is not usually known.

Evaluation and Corrective Action
The results from matrix duplicates are primarily designed to assess the precision of analytical results in a given matrix and are expressed as RPD. Results are compared to established acceptance criteria. If results are outside the criteria, the cause is investigated and corrective actions are taken if necessary, or the matrix duplicate data is reported with appropriate qualifiers. Duplicate analysis results are summarized on the quality control data summary forms.

12.6 Surrogate Standard Analyses

Purpose
Surrogates are used most often in organic chromatography test methods and are chosen to reflect the chemistries of the targeted components of the method. Added prior to sample preparation/extraction, they provide a measure of recovery for every sample matrix.

Frequency
Except where the matrix precludes its use or when not available, surrogate compounds are added to all samples, standards, and blanks for all appropriate test methods.

Composition
Surrogate compounds are chosen to represent the various chemistries of the target analytes in the method. Individual method SOPs specify the surrogate compound(s) used.

Evaluation Criteria and Corrective Action
Surrogate results are calculated in percent recovery (see section 11.3). Results are compared to established acceptance criteria. Surrogates outside the acceptance criteria are evaluated for the effect indicated for the individual sample results. Corrective actions are taken if necessary, or affected results are reported with appropriate qualifiers. Surrogate results are reported with associated sample results.

12.7 Proficiency Testing (PT) Samples

Purpose
PT samples are blind samples purchased from a certified provider. They are used to evaluate the performance of the total analytical system, including all preparation and analysis steps. They are processed under the same conditions and in the same manner as client samples.

Frequency
F&BI participates in certified proficiency testing programs at a frequency required by accrediting agencies. PT samples are analyzed twice a year for each analyte, method and matrix, when available, for which F&BI is accredited.

Composition
PT samples are either prepared in a clean matrix by the provider, or are prepared in a clean matrix at the laboratory according to the provider's instructions. The specific analyte spiking levels are unknown to the laboratory.

Evaluation Criteria and Corrective Action
PT results are evaluated by the provider and reported directly to the regulatory agency as well as to the laboratory. Any PT results which are reported as not acceptable are reviewed and corrective actions implemented as needed. Reports received from PT sample providers and corrective action documentation are kept on file.

F&BI does not send any PT sample, or portion of a PT sample, to another laboratory for any analysis. Also, F&BI does not knowingly receive any PT sample, or portion of a PT sample, from another laboratory, or communicate with another laboratory concerning PT samples.

Table 12-1
QC Frequency and Acceptance Limits Summary
(For Accredited Analysis. Method requirements may supersede these.)

Quality Control Element	Frequency	Acceptance Limits
Method Detection Limit (MDL)	Initially, annually, and with substantial change to method or instrument.	40CFR Part 136, Appendix B calculations.
Demonstration of Capability (DOC)	Annually for each analyst.	Average of replicates within method established control limits of true value, and not >20% RSD for each analyte.
Initial Calibration	Initially and if ICV or CCV fail.	Per method specific requirements.
Initial Calibration Verification (ICV/Second Source)	Following every initial calibration, prior to sample analysis.	Per method specific requirements.
Continuing Calibration Verification (CCV)	When an initial calibration has not been performed: i) At the beginning and end of analysis of 20 samples (max). Concentrations vary. ii) At the beginning of 12 hour shift if internal calibration used.	Per method specific requirements.
Method Blank (MB)	1 per preparation batch of 20 (or fewer) samples.	Concentration for each analyte below RL.
Laboratory Control Sample (LCS)	1 per preparation batch of 20 (or fewer) samples.	Per laboratory established control limits (or default limits.)
Matrix Spike (MS)	1 per preparation batch of 20 (or fewer) samples.	-Per laboratory established control limits (or default limits.) -Does not control batch.
Duplicate Analysis (Sample Duplicate (Dup), MSD or LCSD)	1 per preparation batch of 20 (or fewer) samples. i) Dup or MSD if sufficient sample. ii) LCSD if not.	-Percent recovery per laboratory established control limits (or default limits.) -RPD 0% to 20%. -Dup and MSD do not control batch.
Surrogate	Each field and QC sample for accredited organic analyses.	Per laboratory established control limits (or default limits.)
Proficiency Testing (PT) Samples	Twice per year per accredited method/analyte/matrix.	Per PT provider.

13.0 CORRECTIVE ACTIONS

Corrective actions may be implemented as a result of failure of quality control results to meet established criteria, failure of reported results to meet client's needs, or deviation from established policies and procedures in the SOPs and this QA manual. These are documented with the non-conformance report form which includes an investigation of the root cause, identification of possible corrective actions, and a description of the corrective action taken.

The QA officer reviews each non-conformance report form. This documentation is kept on file with each affected client report, and a copy is kept by the QA officer. During the annual internal audit (see section 16), the QA officer reviews all non-conformance report forms to look for chronic systematic problems that need more in-depth investigation and alternative corrective action consideration.

In addition, corrective actions may be implemented as a result of internal or external audit findings, or management review (see section 16). These are documented with the internal audit corrective action form, external audit correspondence, and the management review corrective action form respectively.

If corrective action procedures do not resolve or identify the problem, personnel will notify management for direction to take. The findings and actions taken are documented and sent to the QA officer for follow-up during an internal audit.

13.1 QC Analysis Failure

If any quality control results fail to meet established criteria, corrective action procedures are immediately implemented if possible. Corrective actions are identified by the individual responsible for a particular analytical method or instrument. In addition, the analyst performing data calculation or review may initiate corrective actions if needed. Corrective actions may include a review of calculations, a check of instrument maintenance, a review of analytical techniques, and reanalysis of affected samples. Table 13-1 has a general summary of QC analyses and corrective actions. Individual method SOPs detail method specific corrective actions. Corrective actions are documented by the analyst in the analysis records.

If, following corrective actions, quality control results still fail, then affected results are reported with appropriate qualifying flags and the analyst uses a non-conformance report form to document. In some cases it may not be possible to follow standard QC procedures and/or corrective actions. For example, if insufficient sample is provided, duplicate sample analysis, matrix spike analysis and/or sample re-extraction may not be possible. In these cases, all possible QC procedures are followed, reported data is qualified if needed, and the analyst uses the extraction worksheet, sequence tables, injection logs, and/or non-conformance report form to document.

If the quality control failure may require that analysis is halted for a particular method and/or instrument, it is the responsibility of the analyst to notify his/her supervisor. The supervisor then determines the required action and notifies the

laboratory/technical director if analysis should be halted. The analysis can then be resumed only after approval from the laboratory/technical director.

13.2 Client Complaints

Any client complaints are resolved promptly. The project manager has primary responsibility for handing client complaints. Complaints which are not able to be resolved by the project manager may be referred to the laboratory/technical director or executive committee. Complaints are documented by the project manager using the non-conformance report form.

13.3 Deviation from SOPs or QA Manual

Deviations from established policies and procedures as written in laboratory SOPs and this QA manual are documented using the extraction worksheet, sequence tables, injection logs, and/or other documents such as the non-conformance report form. A deviation may occur due to a specific client request, or due to laboratory circumstances.

13.4 Audit Findings

Corrective actions needed as a result of audit findings (internal or external) are initiated by the quality assurance manager or the laboratory/technical director. Audit related corrective actions may include providing additional staff training, updating SOPs or establishing new procedures. Internal audit corrective action documentation is kept on file with internal audit findings. External audit corrective actions are documented through correspondence with the auditor(s).

13.5 Record-Keeping Errors

Entries in records are not obliterated by methods such as erasures, overwritten files or markings. Corrections to record-keeping errors are made by one line marked through the error. The individual making the correction initials and dates the correction, and writes a brief explanation as needed. These criteria are also followed for electronically maintained records as applicable.

13.6 Corrective Actions Which Affect Reported Results

If audits or further data review indicate a substantial error in any data which has already been issued in a final report, the client is notified within 30 days and an amended report is issued if necessary.

Table 13-1
QC Corrective Actions
(For Accredited Analysis. Method requirements may supersede these.)

Quality Control Element	Corrective Action(s)	Documentation
Method Detection Limit (MDL)	Determine source of problem, correct, reanalyze (re-extract if necessary).	-Instrument raw data.
Demonstration of Capability (DOC)	Determine source of problem, correct, reanalyze (re-extract if necessary).	-Instrument raw data. -DOC Certificate
Initial Calibration	Determine source of problem and recalibrate. Reanalyze any affected samples.	-Instrument raw data. -Flag sample results if not corrected. -Non-Conformance Form if not corrected.
Initial Calibration Verification (ICV/Second Source)	Re-inject ICV. If ICV fails a second time, a new initial calibration is required. Reanalyze any affected samples.	-Instrument raw data. -Flag sample results if not corrected. -Non-Conformance Form if not corrected.
Continuing Calibration Verification (CCV)	Determine source of problem and re-inject CCV. If second CCV fails, either correct problem and pass two consecutive CCVs, or a new initial calibration is required. Reanalyze any affected samples unless: i) CCV is high and sample is ND. ii) CCV is low and sample result is above regulatory/action limit.	-Instrument raw data. -Flag sample results if not corrected. -Non-Conformance Form if not corrected.
Method Blank (MB)	Reduce background contamination. Re-extract and reanalyze MB and all affected samples in batch. Sample result can be reported if MB is <1/10 of sample result, or if sample is ND.	-Instrument raw data. -Flag MB and sample results if not corrected. -Non-Conformance Form if not corrected.
Laboratory Control Sample (LCS/LCSD)	Determine source of problem. Correct and: i) If instrument related, reanalyze LCS and all affected samples in batch. ii) If spike related, re-extract and reanalyze LCS. iii) If other, re-extract and reanalyze LCS and all affected samples in batch.	-Instrument raw data. -Flag LCS and sample results if not corrected. -Non-Conformance Form if not corrected.

Note: Verify calculations prior to other corrective actions.

Table 13-1
QC Corrective Actions (continued)
(For Accredited Analysis. Method requirements may supersede these.)

Quality Control Element	Corrective Action(s)	Documentation
Matrix Spike (MS)	Determine source of problem. i) If instrument related, reanalyze MS and all affected samples in batch. ii) If spike related, re-extract and reanalyze MS. iii) If LCS passes, flag failing MS result as matrix effect.	-Instrument raw data. -Flag MS result if not corrected. -Non-Conformance Form if not corrected.
Duplicate Analysis (Sample Duplicate (Dup), or MSD)	Determine source of problem. i) If instrument related, reanalyze duplicate and all affected samples in batch. ii) If other, re-extract and reanalyze sample and duplicate (or MS and MSD). iii) If LCS passes, flag failing result as matrix effect.	-Instrument raw data. -Flag duplicate result if not corrected. -Non-Conformance Form if not corrected.
Surrogate	Determine source of problem. i) If instrument related, reanalyze sample. ii) If spike related, re-extract and reanalyze sample. iii) If matrix related, flag failing result as matrix effect.	-Instrument raw data. -Flag surrogate result if not corrected. -Non-Conformance Form if not corrected.
Proficiency Testing (PT) Samples	Determine and correct source of problem. Pass minimum of 2 of last 3 for each accredited method/analyte/matrix.	-PT provider report. -Corrective action letters to regulatory agency.

Note: Verify calculations prior to other corrective actions.

14.0 DATA PROCESSING, VALIDATION, AND REPORTING

All analytical data reported by F&BI to a client in a final report is calculated, reviewed and validated, following established quality system procedures. Individual method SOPs describe specific calculation procedures. The following describes our general data reduction, validation and reporting procedures.

14.1 Data Processing and Review

Analytical results are generated from raw data by the analyst, using procedures specific to the analytical methods, and described in the appropriate method SOP. Results for most analysis are generated by computer. However, analysts usually enter data, such as sample volume/weight, to complete the calculations. Summary pages containing these entries are printed for review. Data generated is electronically transferred into the proper electronic form(s) for reporting. These forms are also printed for review.

For analyses which do not have computer generated data, results are hand entered into the computer for reporting. These results are printed and a 100% review of calculations and data entry is completed. If a particular result, which would normally be computer generated, is manually calculated (usually due to a manual integration) then the entire calculation is documented clearly so that the review analyst can perform a complete review.

Manual Integrations

Integration settings are adjusted to minimize the need for manual integrations. However, a manual integration is necessary if the automatic integration of the peak or integration area (for TPH analyses) is clearly affected (e.g. does not extend from baseline to baseline, peak is split, integration is inconsistent between full strength and diluted peak).

If manual integration is performed, this is clearly documented. The raw data affected by the re-integration is printed and included in the instrument data package, and any manual calculations which are done as a result, are documented. In addition, all manual integrations are reviewed carefully to check for bias.

Quality Control Results

The analyst also calculates and evaluates all quality control results. Analytical data for quality control samples (e.g. method blank, LCS, MS) are calculated and reviewed in the same manner as for all other samples. Results are evaluated using established acceptance criteria, and corrective actions are taken prior to releasing, as final, any associated sample results. After all calculations and QC evaluations are complete, the analyst signs the worksheet(s) and gives it to the calculation review analyst.

Calculation Review

An analyst, independent from the person performing the analysis, is responsible for a 100% review of all raw data, calculations, transcriptions (if needed) and results. Each worksheet reviewed is initialed. Corrections are reviewed by the calculations analyst,

and any disagreements are resolved by the QA officer. Upon completion of review, worksheets are given to the project manager to generate a final report.

14.2 Analytical Data Reports

Analytical data and quality control data are summarized in standard report formats, either designed by F&BI or supplied by the client. The project manager combines the electronic files of reviewed analytical results to generate a final report. Prior to release of the report to the client, the project manager reviews and approves the entire report for completeness, and to ensure that any client-specified objectives were successfully achieved. The project manager then electronically releases the final report file to office personnel to generate a hardcopy report. Specific procedures for generating a final analytical report are provided in the "Creating Reports" SOP. The following information is included in each final analytical data report issued by F&BI.

- The F&BI name, address and phone number, and project manager's name and signature.
- The client's project number/name, the F&BI project number, and date of issue (all on each page).
- The sample identification provided by the client and the sample identification number assigned by F&BI
- Chemical parameters analyzed, reported values, and units of measurement
- Reporting limit of the analytical procedure
- The dates the samples were received and analyzed
- A summary of quality control sample results
- Footnotes referenced to specific data if required to explain/qualify reported values

Explanatory text or the cover letter may also include:

- Person(s) receiving and transmitting the data
- Documentation of samples which did not meet acceptance criteria when received
- Brief discussion of samples analyzed and the analytical program
- Discussion of any apparent data anomalies
- Reference to specific accreditation requirements

Reports for Additional Results

If additional analysis are requested after a final report for a specific laboratory project has been issued, then those additional results are issued in a separate report. A statement that these are additional results for the project is included in the cover letter.

Reports Including Subcontracted Analysis

If any analysis is subcontracted to another laboratory, a statement is included in the cover letter and/or case narrative indicating the subcontracting laboratory and the analysis they performed. The original copy of the subcontracting laboratory's report is provided to the client and a copy is kept with the F&BI project file. No subcontracted work is ever reported as being F&BI data.

Report Review

After the hardcopy data report is prepared, the report is subject to a complete review by another reviewer who is under the supervision of the QA officer. Entries such as

dates, sample IDs, names and addresses are reviewed. The reviewer completes a report review checklist and attaches it to the report. If any errors are found, they are noted and the report is given back to the project leader to correct.

The final draft is reviewed by the executive committee or its designee to assure that all of the steps listed to this point have been followed. He/She then initials the draft which is filed. After approval, a final report bearing the appropriate signatures is issued to the client.

Amending Issued Final Reports

After issuance of a final report, the laboratory report remains unchanged. If a report which has already been issued as final to the client is amended, the amended report is issued separately. A cover letter is included, which states that amended results are being provided. If needed, further explanation of the amendment is included in the cover letter. All amended reports receive final approval before being released to the client.

15.0 DOCUMENT CONTROL AND RECORDS MANAGEMENT

15.1 Document Control

Internally generated documents which are used to define and implement the quality system are controlled. This includes the Quality Assurance Manual, all SOPs and laboratory logbooks. Documents are controlled in two ways. Each document clearly indicates the effective date of the document, the revision number, and the signature(s) of the approving authority (revision number and signature may not be applicable for logbooks). In addition, a record is kept of who received a signed copy of each document.

Preparation of Controlled Documents

Quality system documents are written by the personnel most familiar with the procedures described. The author of the document is responsible for including the correct revision number and date. The documents are reviewed and released by the QA officer, laboratory/technical director and/or executive committee representative as applicable. They are implemented on the revision date indicated on the document. More specific procedures for writing and organizing quality system documents are described in the "Quality System Document Organization" SOP.

Office personnel are responsible for controlling logbooks. Laboratory logbooks are sequentially assigned a number, which is clearly written on the logbook. The name/use, and starting date of the logbook are also written on the logbook and are recorded in the Master Log of Laboratory Logbooks. Completed logbooks are filed with office records, or with the associated instrument, if applicable.

Revision of Controlled Documents

Currently existing quality system documents are reviewed annually during the internal laboratory audit (see section 16). Documents may be revised due to changes initiated by an internal or external audit; or due to changes such as new instrumentation, updated instrument parameters, updated concentrations used for chemical standards etc. A new quality system document is generated if a new quality system procedure is implemented.

To ensure that the beginning and ending effective dates for a document are clearly documented, revision numbers are always whole numbers (starting with revision 1) which are increased by one whole number for each document revision. Therefore the beginning date of a particular revision is the ending date for the immediately previous revision.

Documentation of Controlled Documents

Office personnel are responsible for keeping a record of who received each signed controlled document. The Controlled Document Record includes the document name, a sequentially assigned number which is written on the document before releasing, the person (or company) the document was released to, and the date released. Unsigned copies of documents are not considered controlled.

15.2 Records Management

The purpose of the Records Management system is to standardize the organization, storage and retrieval of all data and documents pertinent to quality and the analytical process. Also, in many cases, F&BI project files must be legally defensible, that is, admissible by the courts and believed as fact. To fulfill these documentation requirements, F&BI maintains a Records Management System which meets the following criteria:

- Data and documents are indexed and easily retrievable.
- Files are secure.
- A formal document inventory can be produced if required by the contract/project.
- Laboratory operation/QC documents are cross referenced to applicable projects.
- The system is documented in the Quality Assurance Manual and Standard Operating Procedures.
- Specific regulatory or contractual requirements can be accommodated.

Analysis Records

Data generated using instruments driven by computers is stored on computer disks coded by the instrument number and date the samples were analyzed. Hard copies of all of the electronic data are also kept. For each instrument, a list of all samples analyzed for each date is kept for easy sample searching. For instruments not controlled by a computer, data is recorded in individual instrument logbooks.

Worksheets are documents filled out by extraction analysts as a sample is processed. These sheets contain measurements such as the weight of the sub-sample, identification and volume of solvent used for any extraction, and documentation of any dilutions or concentrations made. These worksheets are kept with our file copy of any report that is sent to a client.

Laboratory Files

Laboratory records/documents are of two types:

1) Project/Client Files - Documents which are specific to a project/client. All records pertaining to a specific project contain a reference to the laboratory project number which is assigned during sample check-in.
2) Laboratory Files - Documents which pertain to the overall functioning of the laboratory

Project/Client files contain the following:

- Chain-of-Custody documents for the project
- Extraction worksheets for the project
- Electronic file of data generated by Analyst for each sample delivery group and analysis
- Electronic file of compiled data for the results of analyses for each sample delivery group generated by Project Manager
- Non-conformance report forms for the project
- Contract files pertinent to a client
- Communication records between project management and the client
- Final reports submitted to the client

Laboratory files contain the following:

- Sample Check-in Logbook
- Raw instrument data, including calibration data
- Instrument maintenance records
- Internal and external audit records
- Training records
- QA Manual and SOPs
- Any other QA/QC documents pertaining to the overall functioning of the laboratory
- General office/business records

15.3 Archived Records

All files are stored at F&BI, in a safe and secure area, for a minimum of 5 years. Access to archived information is documented with an access log. After 5 years, records are purged only with approval from the executive committee representative.

15.4 Change of Ownership

If there is a change of ownership, records will be retained, and details of record availability will be specified in the transaction.

16.0 QUALITY SYSTEM AUDITS

Quality audits are an essential part of F&BI's quality system program. Two types of audits are used: system audits which qualitatively evaluate the operational details of the quality system program, and performance audits which quantitatively evaluate the outputs of the various measurement systems.

16.1 System Audits

Internal Audits

The QA officer arranges for annual internal audits to verify that laboratory operations continue to comply with the requirements of the quality system. These audits are carried out by trained and qualified personnel who are, wherever possible, independent of the activity to be audited. An internal audit of all or part of the system may also be performed at any time due to any circumstance which raises concern regarding compliance with established policies or procedures, or with the data quality.

Target dates for completion of any corrective action investigations resulting from an internal audit are set within a reasonable time frame so that, if necessary, laboratory practice can be changed and/or clients can be contacted. Where the audit findings indicate a substantial error in calibrations or test results, immediate corrective action is taken and any client whose work was involved is notified within 30 days in writing.

Audit findings and any corrective actions that arise from them are documented using the Internal Audit forms, which are included in Appendix E.

External Audits

F&BI is audited on a regular basis by state and independent auditors, as required for accreditation and by client contracts. External audits are documented through correspondence with the auditors.

Managerial Review

The laboratory/technical director conducts an annual review of the quality system and testing and calibration activities to ensure their continuing suitability and effectiveness, and to introduce any necessary changes or improvements in the quality system and laboratory operations.

The review takes account of reports from managerial and supervisory personnel, the outcome of recent internal and external audits, the results of interlaboratory comparisons or proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, corrective actions, and other relevant factors. In addition, pro-active suggestions for preventive actions are included. These include either technical or quality system improvements which will reduce the likelihood of potential non-conformances.

Review findings and any corrective actions that arise from them are documented using the Managerial Review forms, which are included in Appendix E.

16.2 Performance Audits

In addition to periodic system audits, the quality of results is ensured through ongoing checks which monitor the quality of the laboratory's analytical activities. Examples of such checks are:

- Internal quality control procedures, as described in section 12 above
- Participation in proficiency testing programs, as described in section 12 above
- Use of second source standards and/or certified reference materials
- Replicate analysis using the same or different test methods
- Re-testing of retained samples
- Correlation of results for different but related analysis of a sample
- Review of historical data from the same sample

17.0 CLIENT COMMUNICATION

17.1 Client Confidentiality

Strict client confidentiality is maintained at all times. No records or results are discussed with, or provided to, anyone other than the client unless the client has given specific permission. Clients are notified by the project manager or office personnel whenever any other party requests information about their records.

In addition, when clients require transmission of test results by facsimile, email or other electronic or electromagnetic means, care is taken to ensure that client confidentiality is maintained. To avoid accidental transmission to a different party, commonly used email addresses are included in an email address book, and commonly used fax numbers are pre-programmed. Also, in case of accidental transmission to the wrong party, email messages and facsimile cover sheets contain a message which states that the information is privileged, confidential, and intended only for the addressee named. Office personnel are responsible for maintaining email addresses and pre-programmed fax numbers.

17.2 Review of Requests, Tenders, and Contracts

Before agreeing to a written or oral contract to provide a client with environmental testing services, a review is conducted to ensure that F&BI has the capability and resources necessary to meet the client's requirements. For routine and other simple tasks, the project leader can provide an oral agreement. For more complex tasks, the laboratory/technical director conducts a review. This may include items such as review of previous proficiency testing results, and running trial testing to determine detection limits or other essential quality control requirements. The laboratory's current accreditation status, and any subcontracted work are also reviewed. The client is informed if, at any time before and during the agreement, F&BI is unable to fulfill the requirements of the contract. Records of written contracts, and other communication regarding the contract, are documented in the Client List Excel file, and/or kept in the project/client files.

17.3 Specific Project Communication

After samples have been received, the F&BI project manager communicates with the client, when necessary, regarding sample receipt conditions, specific analysis needs, laboratory capability, and integrity of reported results. Communication is documented in the Client List Excel file, and/or with the Client Communication Record form, which is kept in the project/client files. In addition, any fax or email communication is also kept in the project/client files.

18.0 SUBCONTRACTING ANALYTICAL SAMPLES

It is the policy of F&BI not to subcontract work which we are normally able to perform. For requested analyses which we do not normally perform, the project manager informs the client of the need to subcontract. Work may also be subcontracted if we are temporarily unable to perform one of our normal analyses due to instrument malfunction, or if the client requires certification which we do not have. In these cases the same procedures are followed.

In those cases where we subcontract work, the results reported by the outside laboratory appear under the letterhead of the laboratory reporting the data. Data generated by another laboratory is never reported under our company letterhead. The original report from the contracted laboratory is provided to the client, and a copy is kept with the F&BI project file.

END OF DOCUMENT

APPENDIX A

LIST OF ADMINISTRATIVE SOPS AND QUALITY SYSTEM DOCUMENTS

LIST OF ADMINISTRATIVE SOPS AND QUALITY SYSTEM DOCUMENTS

ADMINISTRATIVE STANDARD OPERATING PROCEDURES	
Title	**Location**
Creating Reports	sops\admin\Reports
Project Manager Procedure (includes Client Communication Record form)	sops\admin\Project Manager
Quality System Document Organization	sops\admin\Document Organization
Sample, Extract, and Waste Disposal	sops\admin\Disposal
Sample Receiving	sops\admin\Sample Receiving
Support Equipment Monitoring and Calibration	sops\admin\Support Equipment
Training Records (includes training forms)	sops\admin\Training
ADDITIONAL QUALITY SYSTEM DOCUMENTS	
Archive Access Log	forms\office\archive
Controlled Document Record	sops\Controlled Document Record
DOC Training Summary Database	fbi\nelap\doc_sum
F&BI Certifications/Accreditations	office records
Final Report Checklist	forms\chklist
Internal Audit/Managerial Review Forms	QAM Appendix E
Laboratory Organization/Personnel Qualifications	fbi\nelap\Lab Organization Chart – Personnel Qualifications
Master Log of Laboratory Logbooks	forms\logbooks\ Master Log
Non-Conformance Report Form	forms\nonconformance
Policy and Health & Safety Manual	sops\Policy and Health & Safety Manual
Quality Assurance Manual	sops\QAM
Sample Condition Upon Receipt Checklist Form	forms\checkin\ SampleCondition
Signature List	office records

APPENDIX B

MAJOR ANALYTICAL EQUIPMENT

MAJOR ANALYTICAL EQUIPMENT

Make/Model	Type	Identifier	Software
Agilent 5890	GC/FID	GC 1	ChemStation
Agilent 5890 with Varian Archon and OI 4560	GC/FID/PID Autosampler Purge & Trap	GC 2	ChemStation
Agilent 5890 with Varian Archon and OI 4560	GC/FID/PID Autosampler Purge & Trap	GC 3	ChemStation
Agilent 5890	GC/FID	GC 4	ChemStation
Agilent 5890	GC/ECD/ECD	GC 5	ChemStation
Agilent 5890	GC/FID	GC 6	ChemStation
Agilent 6890	GC/FID/ECD	GC 7	EnviroQuant
Agilent 5890 with Agilent 5972B	GC MS	GC/MS 2	EnviroQuant
Agilent 6890 with Agilent 5973	GC MSD	GC/MS 3	EnviroQuant
Agilent 6890N with Agilent 5973N and OI 4552 and OI 4560	GC MSD Autosampler Purge & Trap	GC/MS 4	EnviroQuant
Agilent 6890 with Agilent 5973 and OI 4552 and OI 4560	GC MSD Autosampler Purge & Trap	GC/MS 5	EnviroQuant
Agilent 6890 with Agilent 5973	GC MSD	GC/MS 6	EnviroQuant
Agilent 7890A with Agilent 5975C and OI 4552 and OI 4560	GC MSD Autosampler Purge & Trap	GC/MS 7	EnviroQuant
Agilent 6890 with Agilent 5975C	GC MSD	GC/MS 8	EnviroQuant
Perkin Elmer Sciex Elan 9000	ICP/MS	ICP/MS	Elan
Tekran 2600	CVAFS	CVAFS	Tekran
VWR Model 800	Turbidimeter	Turbidimeter	N/A
Orion Research, Model# 420A	pH Meter	pH Meter	N/A
UV-VIS, Shimadzu UV-2450	Spectrophotometer	Spectrophotometer	N/A
Rae Systems, Model# PGM-30 (2)	Hand Held PID	Hand Held PID	N/A

MAJOR ANALYTICAL EQUIPMENT
(Continued)

Make/Model	Type	Identifier	Software
Buck Scientific, Model# HC-404 (1)	IR analyzer	IR analyzer	N/A
Beckman Model TJ-6 (2)	Centrifuge	Centrifuge	N/A
Vortex Genie 2, Model G-560 (3)	Vortex Mixer	Vortex Mixer	N/A
National Appliance, Model #230A (1)	Water Bath	Water Bath	N/A
Organomation Associates, Inc. Model #120 (1)	Water Bath	Water Bath	N/A
Branson Untrasonics Corporation, Model# 450 (2)	Sonicator	Sonicator	N/A
Sonics and Material, Inc. Model# VC600 (1)	Sonicator	Sonicator	N/A
Marathon Electric, Model 0523-N191Q-G588 (1)	Sonicator	Sonicator	N/A
Sonics and Material, Inc. Model# VC750 (2)	Sonicator	Sonicator	N/A
Mettler Electronics Group, Model#ME 4.6 (1)	Cavitator	Cavitator	N/A
AND Model #HA-120M (1)	Analytical Balance	Analytical Balance	N/A
AND Model #ER-120A (1)	Analytical Balance	Analytical Balance	N/A
AND Model #EK-1200A (4)	Analytical Balance	Analytical Balance	N/A
Denver Instrument Model #XP-1500 (3)	Analytical Balance	Analytical Balance	N/A
US Electrical Motors, Model #E438 (1)	Tumbler	Tumbler	N/A
Emerson Electric Co. (2)	Vacuum Pump	Vacuum Pump	N/A
Stabil-Therm Gravity Oven Model#OV-484A (1)	Oven	Oven	N/A
Precision Scientific Group, Model 26 (1)	Mechanical Convention Oven	Mechanical Convention Oven	N/A

MAJOR ANALYTICAL EQUIPMENT
(Continued)

Make/Model	Type	Identifier	Software
Thermolyne Corporation, Model # F6000 (1)	Muffle Furnace	Muffle Furnace	N/A
Barnstead/Thermolyne Model#1415M (1)	Muffle Furnace	Muffle Furnace	N/A
Thermolyne Corporation, Model # HPA2245M (2)	Hot Plate	Hot Plate	N/A
Corning Laboratory, Model#PC-300 (1)	Hot Plate	Hot Plate	N/A
Corning Laboratory Model #PC-520 (1)	Hot Plate/Stirrer	Hot Plate/Stirrer	N/A
Corning Laboratory Model #PC-420 (1)	Hot Plate/Stirrer	Hot Plate/Stirrer	N/A
CPI-MOD Block (70 mL) Digest Heater Block with Controler (2)	Digester/Heater Block	Digester/Heater Block	N/A
Julabo Labortachnik, Model#FC600 (1)	Chilling Unit	Chilling Unit	N/A

APPENDIX C
EQUIPMENT MAINTENANCE PROGRAM
(GENERAL GUIDANCE)

EQUIPMENT MAINTENANCE PROGRAM
(GENERAL GUIDANCE)

Instrument	Activity	Approximate Frequency
GC 1, GC 4, and GC 6 *(Semivolatile TPH)* Agilent 5890 Series II	Clean FID	Weekly or as needed
	Check Gases	Replace at 200 PSI
	Change Liner	Every 200 injections or as needed due to response change
	Change Septum	Every 200 injections
	Replace Syringe	As needed if clogged or broken
	Clip Column	As needed to improve chromatography
	Replace Column	As needed
	Change Gold Seal	As needed
GC 2 and GC 3 *(Volatile TPH and BTEX by 8021B)* Agilent 5890 Series II	Clean FID	Weekly or as needed
	Check Gases	Replace at 200 PSI
	Clean PID	As needed
	Replace PID Lamp	As needed to improve sensitivity
	Replace Column	As needed
OI 4560 Concentrator (GC 2, GC 3, GC/MS 4, GC/MS 5, and GC/MS 7)	Check Purge Flow	Monthly
	Replace Trap	As needed
	Clean Sparge Cell	As needed
	Clean Sparge Filter	As needed if clogged
4552/Archon Autosampler (GC 2, GC 3, GC/MS 4, GC/MS 5, and GC/MS 7)	Tighten Syringe Nut	Once a week
	Autocalibrate	As needed
GC 5 *(PCBs, Organic Lead)* Agilent 5890 Series II	Check Gases	Replace at 200 PSI
	Change Liner	Every 200 injections or as needed due to response change
	Change Septum	Every 200 injections
	Replace Syringe	As needed if clogged or broken
	Clip Column	As needed to improve chromatography
	Replace Column	As needed
	Change Gold Seal	As needed
	Clean ECD	As needed to improve chromatography

EQUIPMENT MAINTENANCE PROGRAM
(GENERAL GUIDANCE)

Instrument	Activity	Approximate Frequency
GC 7 *(HFS, Canadian Pulp)* Agilent 5890 Series II	Clean FID	Weekly or as needed
	Check Gases	Replace at 200 PSI
	Change Liner	Every 200 injections or as needed due to response change
	Change Septum	Every 200 injections
	Replace Syringe	As needed if clogged or broken
	Clip Column	As needed to improve chromatography
	Replace Column	As needed
	Change Gold Seal	As needed
	Clean ECD	As needed to improve chromatography
GC/MS 2, GC/MS 3, GC/MS 6, and GC/MS 8 *(Semivolatiles and Methamphetamine)*	Check Gases	Replace at 200 PSI
	Change Liner	Every 200 injections or if tune fails due to degradation of DDT > 20
	Change Septum	Every 200 injections
	Replace Syringe	As needed if clogged or broken
	Clip Column	As needed to improve chromatography
	Replace Column	As needed
	Change Gold Seal	As needed
	Change Pump Oil	Every 6 months
	Clean Source	As needed
GC/MS 4, GC/MS 5, and GC/MS 7 *(Volatiles)*	Check Gases	Replace at 200 PSI
	Replace Column	As needed
	Change Pump Oil	Every 6 months
	Clean Source	As needed
CVAFS *(Mercury)*	Clean Liquid Gas Separator	Before each run
	Clean Cuvette	As needed
	Replace Lamp	As needed
	Change Tubing	As needed
ICP/MS *(Metals)*	Change Torch	As needed
	Change Tubing	As needed
	Change Cooling Water	As needed
	Clean Cones	As needed

APPENDIX D

SAMPLE CONTAINERS, PRESERVATION, AND HOLDING TIMES

SAMPLE CONTAINERS, PRESERVATION, AND HOLDING TIMES

Parameter	Method	Matrix	Minimum Sample Volume	Container	Preservation	Maximum Holding Time
Organic Analysis						
Diesel Range Organics (Extractable TPH)	8015M NWTPH-Dx AK102	Water	500 mL	500 mL glass	*Cool, =6°C	*7 days to extract, 40 days after extr.
	8015M NWTPH-Dx AK102/103	Soil	50 grams	4 oz glass	Cool, =6°C	14 days to extract, 40 days after extr.
Gasoline Range Organics (Purgable TPH)	8015M NWTPH-Gx AK101	Water	40 mL	40 mL VOA	Cool, =6°C, HCl to pH<2, no headspace	14 days
	8015M NWTPH-Gx	Soil	5 grams	5035 Kit	Freeze within 48 hrs., =0°C	14 days
	AK101	Soil	app. 50 g	4 oz glass septum top	Methanol	28 days
HCID	NWTPH-HCID	Water	500 mL	500 mL glass	Cool, =6°C	7 days to extract, 40 days after extr.
		Soil	50 grams	4 oz glass	Cool, =6°C	14 days
HEM (O&G), SGT-HEM	1664	Water	1 Liter	1 L glass	Cool, =6°C, H_2SO_4 to pH<2	28 days
PCBs	8082A	Water	1 Liter	1 L glass	Cool, =6°C	none
	8082A	Soil	50 grams	4 oz glass	Cool, =6°C	none
PNAs (PAHs)	8270D or 8270D SIM	Water	500 mL	500 mL glass	Cool, =6°C	7 days to extract, 40 days after extr.
	8270D or 8270D SIM	Soil	50 grams	4 oz glass	Cool, =6°C	14 days to extract, 40 days after extr.
Purgable Aromatic Hydrocarbons (BTEX, MTBE)	8021B or AK101	Water	40 mL	40 mL VOA	Cool, =6°C, HCl to pH<2, no headspace	14 days
	8021B	Soil	20 grams	4 oz glass	Cool, =6°C,	14 days
	AK101	Soil	app. 50 g	4 oz glass septum top	Methanol	28 days
Semivolatile Organic Compounds (SVOCs, BNAs)	8270D	Water	1 Liter	1 L glass	Cool, =6°C	7 days to extract, 40 days after extr.
	8270D	Soil	50 grams	4 oz glass	Cool, =6 °C	14 days to extract, 40 days after extr.
Volatile Organic Compounds (VOCs)	8260C	Water	40 mL	40 mL VOA	Cool, =6°C, HCl to pH<2, no headspace	14 days
	8260C	Soil	5 grams	5035 Kits	Freeze within 48 hrs., =0°C	14 days

* For NWTPH-Dx and AK102 methods, if preserved with HCl or H_2SO_4 to pH<2, holding time is 14 days to extract.

SAMPLE CONTAINERS, PRESERVATION, AND HOLDING TIMES

Parameter	Method	Matrix	Minimum Sample Volume	Container	Preservation	Maximum Holding Time
Inorganic Analysis						
Alkalinity	SM2320B	Water	100 mL	500 mL poly	Cool, =6°C	14 days
BOD	405.1	Water	1 Liter	1 L glass	Cool, =6°C	48 hours
Chloride	300.0	Water	100 mL	500 mL poly	Cool, =6°C	28 days
COD	410.4	Water	100 mL	500 mL poly	H_2SO_4 to pH<2	28 days
Conductivity	120.1	Water	100 mL	500 mL poly	Cool, =6°C	28 days
Cyanide, total	335.2	Water	1 Liter	1 L glass	NaOH to pH 12	14 days
Fluoride	300.0	Water	100 mL	500 mL poly	Cool, =6°C	28 days
Hardness	SM2340B	Water	100 mL	500 mL poly	HNO_3 to pH,<2	6 months
Nitrate	300.0	Water	100 mL	500 mL poly	Cool, =6°C	48 hours
Nitrite	300.0	Water	100 mL	500 mL poly	Cool, =6°C	48 hours
Nitrate-Nitrite	353.2	Water	100 mL	500 mL poly	Cool, =6°C, H_2SO_4 to pH<2	28 days
pH	9040/150.1	Water	20 mL	500 mL poly	None	24 hours
	9045	Soil	20 grams	4 oz glass	None	28 days
Phosphorus, total	365.2	Water	100 mL	500 mL poly	Cool, =6°C, H_2SO_4 to pH<2	28 days
Sulfate	300.0	Water	100 mL	500 mL poly	Cool, =6°C	28 days
Sulfide	376.2	Water	500 mL	500 mL poly	Cool, =6°C ZnAcetate plus NaOH to pH>9	7 days
Sulfite	377.1	Water	100 mL	500 mL poly	None	24 hours
Total Dissolved Solids (TDS)	SM2540C/ 160.1	Water	500 mL	500 mL poly	Cool, =6°C	7 days
Total Organic Carbon (TOC)	415.1/ 9060M	Water	100 mL	500 mL poly	H_2SO_4 to pH<2	28 days
Total Suspended Solids (TSS)	SM2540D	Water	250 mL	500 mL poly	Cool, =6°C	7 days
Turbidity	SM2130B	Water	20 mL	500 mL poly	Cool, =6°C	48 hours
Metals Analysis						
Metals (except Cr VI and Mercury)	200.8/6020 or 6010	Water	200 mL	500 mL poly	HNO_3 to pH<2	6 months (2 weeks if not preserved)
	200.8/6020 or 6010	Soil	20 grams	4 oz glass	Cool, =6°C	6 months
Chromium VI	SM3500Cr	Water	100 mL	500 mL poly	Cool, =6°C	24 hours
	7196A	Soil	50 grams	4 oz glass	Cool, =6°C	30 days
Mercury	1631/7040	Water	125 mL	250 mL poly, fluoropolymer, or glass	HNO_3 to pH<2	28 days (48 hours if not preserved)

	1631/7041	Soil	50 grams	4 oz glass	Cool, =6°C	28 days

APPENDIX E

INTERNAL AUDIT/MANAGERIAL REVIEW FORMS

QUALITY ASSURANCE/QUALITY CONTROL
INTERNAL AUDIT

Summary

Areas audited

1. Quality System: *2. Support Equipment* •

Quality Assurance Manual and SOPs reviewed •
(attach "List of Current SOPs" with reviewed documents marked)

3. Non-Conformance reports (review) • *4. Project Management/Reports* •

5. Sample receiving, storage, disposal • *6. Document Control/Training* •

7. Extractions:

Organic		Inorganic		Volatiles	
3510	•	200.8	•	5030	•
3550	•	1631	•	5035	•
3580	•			3580	•
3630	•				

8. Analysis/Calculations:

8260	•	Organic Pb (ECD)	•	TPHD	•	200.8	•
8270	•	Organic Pb (ICP/MS)	•	Cr^{+6}	•	1631	•
8082	•	Methamphetamine	•	pH	•	1664	•
524.2	•	Canadian Pulp	•	Spec. Grav.	•	TSS	•
8011	•	TPHG/BTEX	•	Turbidity	•	Other	• ____

Total number of corrective actions_____

Comments:_____

Does any non-conformance/corrective action require further notification?

Yes • No • (If yes, explain)

_____

_____

Attach all internal audit checksheets and corrective action forms and file in the internal QA/QC audit folder.

QA Officer's Signature_____ Date Audit Review Completed_____

QUALITY ASSURANCE/QUALITY CONTROL
INTERNAL AUDIT

Area: Sample receiving, storage, disposal

Date:_____ Auditor:_____ Person(s) Audited:_____

	YES	NO
Is the Master Sample Log-In book in order?	_____	_____
Are COCs filled out correctly during sample check-in?	_____	_____
Are all samples/projects traceable, i.e. labeled?	_____	_____
Are samples stored in the correct refrigerators?	_____	_____
Are refrigerator temperatures recorded daily?	_____	_____
Are standards/solvents logged in?	_____	_____
Are sample disposal records kept?	_____	_____
Disposal Area:		
Does each drum have an up to date contents list?	_____	_____
Are drums properly labeled?	_____	_____
Are waste materials contained properly in each drum?	_____	_____
Are waste disposal records kept?	_____	_____

Fill out a corrective action form for any "no" answers and for anything else as needed.

Number of corrective actions given:_____ COMMENTS_____

_____

_____

QUALITY ASSURANCE/QUALITY CONTROL
INTERNAL AUDIT

Area: Extractions

Organic • Inorganic • Volatiles •

Method(s): _____ _____ _____

_____ _____ _____

Date:_____ Auditor:_____ Person(s) Audited:_____

	YES	NO	N/A
Are waste containers properly labeled and stored?	_____	_____	_____
Was any new equipment properly validated prior to use?	_____	_____	_____
Are manufacturer's certificates which verify calibration/accuracy available?	_____	_____	_____
Are analytical balances calibrated daily?	_____	_____	_____
Are autopipets calibrated at least monthly?	_____	_____	_____
Are bottle top dispensers calibrated at least monthly?	_____	_____	_____
Is the oven temperature recorded daily?	_____	_____	_____
Is the water bath temperature recorded daily?	_____	_____	_____
Is the hot block temperature recorded daily?	_____	_____	_____
Is equipment which falls out of calibration repaired or taken out of service?	_____	_____	_____

Fill out a corrective action form for any "no" answers and for anything else as needed.

Number of corrective actions given:_____ COMMENTS_____

_____

_____

QUALITY ASSURANCE/QUALITY CONTROL
INTERNAL AUDIT

Area: Analysis/Calculations Method:_____

Date:_____ Auditor:_____ Person(s) Audited:_____

	YES	NO
Are standards traceable to a certified source?	_____	_____
Are standards labeled with an expiration date?	_____	_____
Are standards taken out of use after the expiration date?	_____	_____
Do initial calibrations meet the method requirements?	_____	_____
Are initial calibrations verified with a second source standard?	_____	_____
Are initial calibrations verified with continuing calibration verification standards?	_____	_____
Do QC sample results (method blanks, LCS, MS) meet the method requirements?	_____	_____
Are corrective actions taken for any result which falls outside of acceptance criteria?	_____	_____
Are control charts up to date?	_____	_____
Are instrument maintenance logs up to date?	_____	_____
Are MDLs up to date?	_____	_____
Are reporting limits based on MDLs?	_____	_____
Are data calculations based on the initial calibration?	_____	_____
Is data flagged with qualifiers if necessary?	_____	_____

Fill out a corrective action form for any "no" answers and for anything else as needed.

Number of corrective actions given:_____ COMMENTS_____

_____

QUALITY ASSURANCE/QUALITY CONTROL
INTERNAL AUDIT

Area: Project Management/Reports

Date:_____ Auditor:_____ Person(s) Audited:_____

	YES	NO
Are extraction worksheets filled out completely and clearly?	_____	_____
Are capability issues communicated to the client and clearly documented?	_____	_____
Are any changes to the COC initialed/dated with the name of the person requesting the change clearly indicated?	_____	_____
Is the Subcontract Fax Coversheet used for subcontracted samples?	_____	_____
Is the Non-Conformance form used to document client complaints?	_____	_____
Are subcontract lab reports forwarded without change to the client, and clearly identified in our final report?	_____	_____
Are amended reports clearly identified?	_____	_____
Are additional reports clearly identified?	_____	_____
Are draft results/reports clearly identified?	_____	_____
Are flags from analysts left as is?	_____	_____
Is data flagged in an unambiguous manner?	_____	_____
Is there a case narrative when the validity of the data is in question?	_____	_____

Fill out a corrective action form for any "no" answers and for anything else as needed.

Number of corrective actions given:_____ COMMENTS_____

_____

QUALITY ASSURANCE/QUALITY CONTROL
INTERNAL AUDIT

Area: Document Control/Training

Date:_____ Auditor:_____ Person(s) Audited:_____

	YES	NO
Is the employeed signature list up to date?	_____	_____
Are all logbooks numbered and listed in the Master Log of Laboratory Logbooks?	_____	_____
Is the Controlled Document Record used to track distribution of controlled documents?	_____	_____
Is the Archive Access Log used?	_____	_____
Is the List of Current SOPs up to date?	_____	_____
Are the Current SOP binders up to date?	_____	_____
Do Employee Attestation forms list current SOPs and revision numbers?	_____	_____
Have employees initialed Attestation forms for the current revision of all applicable SOPs?	_____	_____
Are DOCs complete and clearly identified?	_____	_____
Is the DOC training summary database up to date?	_____	_____
Are Laboratory Organization and Personnel Qualifications summaries up to date?	_____	_____
Is current accreditation summary up to date?	_____	_____

Fill out a corrective action form for any "no" answers and for anything else as needed.

Number of corrective actions given:_____ COMMENTS_____

_____

_____

QUALITY ASSURANCE/QUALITY CONTROL
INTERNAL AUDIT

Area: Support Equipment

Date:_____ Auditor:_____ Person(s) Audited:_____

	YES	NO
Are primary reference weights and thermometers clearly labeled?	_____	_____
Are standards NIST traceable?	_____	_____
Are daily standards referenced in logbooks?	_____	_____
Are logbooks (refrigerator, water bath, hot block, oven, balance autopipete, etc.) completed as required?	_____	_____
Are logbooks (refrigerator, water bath, hot block, oven, balance autopipete, etc.) bound or in a 3 ring binder?	_____	_____
Is all calibrated support equipment (thermometers, autopipetes, bottle top dispensers, hot blocks, etc.) clearly labeled?	_____	_____
If any equipment is out of specifications, is it taken out of service and clearly labeled as such?	_____	_____

Fill out a corrective action form for any "no" answers and for anything else as needed.

Number of corrective actions given:_____ COMMENTS_____

INTERNAL QA/QC AUDIT CORRECTIVE ACTION

Area/Analysis_____

Corrective action given to (name):_____

Given by (name):_____
(Keep a copy of this form for tracking)

Date given:_____ Target response date:_____
(set based on potential need to notify clients and on work load)

Description of non-compliance:_____

Description of required corrective action:_____

Specific documentation required: (Return this form to the auditor with the required documentation attached.)

Corrective action reviewed and approved:

QC Officer (or designee):_____ Date:_____

(Return this form to QC officer along with attached documentation)

QUALITY SYSTEM
MANAGERIAL REVIEW

Date:_____ Auditor:_____

Review of Calendar Year 20___

Write comments, as needed, in a separate file and attach.

1. Review of most recent internal audit (Date(s)_____)

   - All areas audited Yes • No •
   - Corrective actions implemented and documented Yes • No •

2. Review of non-conformance reports

   - Corrective actions implemented and documented Yes • No •

3. Review of proficiency testing (PT) samples

   - Analysis completed two times per year per analyte per matrix (for NELAP accredited analyses) Yes • No •
   - Corrective actions implemented and documented Yes • No •

4. Review of current accreditation status.

5. Review of recent audits/assessments by external bodies.

   - External audit(s) by: State/Company_____ Date_____
   - Corrective actions implemented and documented. Yes • No •

6. If audits or data review resulted in changes to previously reported data, were affected clients notified within 30 days? Yes • No • n/a •

7. Changes in volume and/or type of work undertaken which may affect quality.

8. Feedback from clients regarding quality. (Include review of any client complaints.)

9. Other relevant factor(s) which may affect quality.

10. Pro-active preventive actions to avoid potential non-conformances.

MANAGERIAL REVIEW CORRECTIVE ACTION

Area/Analysis_____

Corrective action given to (name):_____

Given by (name):_____
(Keep a copy for tracking)

Date given:_____ Target Response Date:_____
(set based on potential need to notify clients and on work load)

Description of non-compliance:_____

_____

_____

Description of required corrective action:_____

_____

_____

_____

Specific documentation required: (Return this sheet to the auditor with the required documentation attached.)

_____

_____

_____

Corrective action reviewed and approved:

Name:_____ Date:_____
(Technical/Laboratory Director or designee)

File along with attached documentation in the management review folder.

APPENDIX F

DEFINITIONS

DEFINITIONS

Acceptance Criteria: specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

Accrediting Authority: the Territorial, State, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation. (NELAC)

Accuracy: the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Analyst: the designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (NELAC)

Audit: a systematic evaluation to determine the conformance to quantitative *and qualitative* specifications of some operational function or activity. (EPA-QAD)

Batch: environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one to 20 environmental samples of the same matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. (NELAC Quality Systems Committee)

Blank: a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

- Equipment Blank: a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)
- Field Blank: blank prepared in the field by filling a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)
- Instrument Blank: a clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

- Method Blank: a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses. (NELAC)
- Reagent Blank: (method reagent blank): a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

Blind Sample: a sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (NELAC)

Calibration: to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. (NELAC)

Calibration Curve: the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

Calibration Standard: a substance or reference material used to calibrate an instrument. (QAMS)

Certified Reference Material (CRM): a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 - 2.2)

Chain of Custody Form: record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; collector; time of collection; preservation; and requested analyses. (NELAC)

Confirmation: verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to: Second column confirmation, Alternate wavelength, Derivatization, Mass spectral interpretation, Alternative detectors or, Additional cleanup procedures. (NELAC)

Conformance: an affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994)

Corrective Action: the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit: a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria). (NELAC)

Data Reduction: the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)

Demonstration of Capability: a procedure to establish the ability of the analyst to generate acceptable accuracy. (NELAC)

Document Control: the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed. (ASQC)

Holding Times (Maximum Allowable Holding Times): the maximum times that samples may be held prior to analysis and still be considered valid or not compromised. (40 CFR Part 136)

Internal Standard: a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. (NELAC)

Laboratory: a body that calibrates and/or tests. (ISO 25)

Laboratory Control Sample (LCS): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (NELAC)

Laboratory Control Sample Duplicate (LCSD): a second replicate LCS prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (QAMS)

Matrix: the substrate of a test sample.

Laboratory Duplicate: aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

Matrix Spike (MS): a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target

analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (QAMS)

Matrix Spike Duplicate (MSD): a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (QAMS)

Method: see Test Method

Method Detection Limit: the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136, Appendix B)

National Institute of Standards and Technology (NIST): an agency of the US Department of Commerce's Technology Administration that is working with EPA, States, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested States can be accredited by NIST to provide NIST-traceable proficiency testing (PT) to those laboratories testing drinking water and wastewater. (NIST)

National Environmental Laboratory Accreditation Conference (NELAC): a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

National Environmental Laboratory Accreditation Program (NELAP): the overall National Environmental Laboratory Accreditation Program of which NELAC is a part. (NELAC)

National Voluntary Laboratory Accreditation Program (NVLAP): a program administered by NIST that is used by providers of proficiency testing to gain accreditation for all compounds/matrices for which NVLAP accreditation is available, and for which the provider intends to provide NELAP PT samples. (NELAC)

Performance Audit: the routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

Performance Based Measurement System (PBMS): a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified and serve as criteria for selecting measurement processes which will meet those needs in a cost-effective manner. (NELAC)

Precision: the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (NELAC)

Preservation: refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample. (NELAC)

Proficiency Testing: a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (NELAC)

Proficiency Testing Study Provider: any person, private party, or government entity that meets stringent criteria to produce and distribute NELAC PT samples, evaluate study results against published performance criteria and report the results to the laboratories, primary accrediting authorities, PTOB/PTPA, and NELAP. (NELAC)

Proficiency Test Sample (PT): a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

Protocol: a detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed. (EPA-QAD)

Quality Assurance: an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

Quality Assurance [Project] Plan (QAPP): a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EPA-QAD)

Quality Control: the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. (QAMS)

Quality Control Sample: an uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (EPA-QAD)

Quality Manual: a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (NELAC)

Quality System: a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC. (ANSI/ASQC E-41994)

Quantitation Limits: levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported at a specified degree of confidence. (NELAC)

Range: the difference between the minimum and the maximum of a set of values. (EPA-QAD)

Raw Data: any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted. (EPA-QAD)

Reference Material: a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (ISO Guide 30-2.1)

Reference Method: a method of known and documented accuracy and precision issued by an organization recognized as competent to do so. (NELAC)

Reference Standard: a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM-6.08)

Replicate Analyses: the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval. (NELAC)

Reporting Limits: routinely reported lower limits of quantitation, typically 2 to 10 times the MDL.

Sample Tracking: procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples. (NELAC)

Selectivity: the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. (EPA-QAD)

Sensitivity: the capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (NELAC)

Spike: a known mass of target analyte added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes. (NELAC)

Standard Operating Procedures (SOPs): a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks. (QAMS)

Standardized Reference Material (SRM): a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method. (EPA-QAD)

Supervisor (however named): the individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses. (NELAC)

Surrogate: a substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes. (QAMS)

Technical Director: individual(s) who has overall responsibility for the technical operation of the environmental testing laboratory. (NELAC)

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate. (ISO/IEC Guide 2-12.1, amended)

Test Method: an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP or published by a recognized authority. (NELAC)

Testing Laboratory: a laboratory that performs tests. (ISO/IEC Guide 2-12.4)

The NELAC Institute (TNI): A non-profic organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive and transparent process that is responsive to the needs of the community. (TNI)

Traceability: the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)

United States Environmental Protection Agency (EPA): the federal governmental agency with responsibility for protecting public health and safeguarding and improving the natural environment (i.e., the air, water, and land) upon which human life depends. (US-EPA)

Validation: the process of substantiating specified performance criteria. (EPA-QAD)

Verification: confirmation by examination and provision of evidence that specified requirements have been met. (NELAC)

Sources:
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